North Dakota Health Information Technology

Quality Healthcare for all North Dakotans - Anywhere, Anytime

Technical Infrastructure Domain Team

WORKING DRAFT DOCUMENT v2

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Contents

1. Meaningful Use

The Department of Health and Human Services and the Office of the National Coordinator (ONC) for Health Information Technology (HIT) and Centers for Medicare and Medicaid Services (CMS) have recently released the Meaning Use (MU) final rule specifying the related initial set of standards, implementation specifications, and certification criteria for Electronic Health Record (EHR) technology with final Meaningful Use Stage 1 objectives and measures. This document fully recognizes the final rules along with Meaningful Use Stage 1 objectives and measures and the technical infrastructure reflects meaningful use objectives and adopted standards, implementation specifications, and certification criteria in the design of HIE architecture, on planning of initial set of services, and in adoption of initial set of standards and implementation specifications realizing the initial set of services. Appendix A contains a table of summaries of final rule for Meaningful Use Certification Criteria for Health Information Technology released by CMS and ONC. The last column of the table, "IHE Stage 1" indicates a set of standards/implementation specifications recommended for content exchange, vocabulary, and security/privacy to be adopted for the first stage (Stage 1) of the Health Information Exchange (HIE) implementation as well as a set of capabilities to be offered at the Stage 1 of the HIE implementations. The following list identifies as a minimum set of services to be offered for the Stage 1 aligned with general and ambulatory/inpatient specific capabilities as specified in the Meaningful Use final rule.

- Electronic Prescribing Service: Electronic generation and transmission of prescriptions and prescription related information
- Laboratory Results Exchange Service: Electronic submission of laboratory test orders and receiving/displaying of laboratory test results
- Exchange of Patient Summary Record in the format of HL7 CDA Release 2, Continuity of Care Document (CCD)[1] with following minimum data elements:
- Demographics
- Problem list
- Medication & Medication Allergy List
- Laboratory test results
- Procedures

The following sections describe standards and implementation specifications adopted for Meaningful Use.

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[1] HITSP/C32 "Summary Documents Using HL7 CCD Component" as an implementation specification to be adopted

1.1. Adopted Standards for Meaningful Use

Category for Standards to support meaningful use

Category	Description
Vocabulary Standards	Standardized nomenclatures and code sets used to describe clinical information such as problems and procedures, medications, and allergies etc
Content Exchange Standards	Standards used to share clinical contents between healthcare stakeholders: patient record summaries, prescriptions, structured clinical documents, and administrative transactions
Transport Standards	Standards used to establish a common, predictable, secure communication channel for exchange of clinical contents between health information systems.
Privacy and Security Standards	Standards related security and privacy: Authentication, Authorization, Access Control, and Auditing

1.1.1. Vocabulary Standards

The State of North Dakota should adhere to semantic interoperability and standards for coding systems

Purpose		Meaningful Use Stage 1	Meaningful Use Stage 2
Electronic Prescribing		National Library of Medicine's RxNorm	RxNorm
Patient Summary Record	Medication Allergy List	No Standard	Unique Ingredient Identifier (UNII)
	Medication List	National Library of Medicine's RxNorm	RxNorm
	Problem List	ICD-9-CM or SNOMED-CT	ICD-10-CM or SNOMED CT
	Procedures	45 CFR 162.1002 (a)(2) and (a)(5)	

	Lab Order and Results	LOINC	LOINC
Lab Results reporting to Public Health		LOINC	LOINIC, UCUM, SNOMED-CT
Surveillance Reporting to Public Health		HL7 2.3.1 or HL7 2.5.1	GIPSE
Submission to Immunization Registries		CVX	CVX

1.1.2. Content Exchange Standards

Purpose	Meaningful Use Stage 1	Meaningful Use Stage 2
Electronic Prescribing	NCPDP SCRIPT 8.1 or SCRIPT 10.6	NCPDP SCRIPT 10.6
Drug Formulary Check	NCPDP Formulary and Benefits Standards 1.0	NCPDP Formulary and Benefits Standards 1.0
Patient Summary Record	HL7 CDA R2 CCD Level 2 (HITSP C32) or ASTM CCR	TBD
Administrative Transactions	HIPAA Transaction Standards ASC X12N or NCPDP	HIPAA Transaction Standards ASC X12N or NCPDP ▪ ASC X12N 270/271 ▪ ASX X12N 837 (Dental, Professional, and Institutional) ▪ Other transactions
Quality Reporting	CMS PQRI	CMS PQRI
Lab Results reporting to Public Health	HL7 2.5.1	TBD
Surveillance Reporting to Public Health	HL7 2.3.1 or 2.5.1	TBD
Submission to Immunization Registries	HL7 2.3.1 or 2.5.1	TBD

1.1.3. Transport Standards

- Simple Object Access Protocol (SOAP)
- Representational State Transfer (REST)
- HTTP
- eXtensible Markup Language (XML)

1.1.4. Privacy and Security Standards

Purpose	Adopted Standards
General Encryption and Description of Electronic Health Record	FIPS 197 Advanced Encryption Standard (AES)
Encryption/Decryption of Electronic Health Information for Exchange	Secure communication channel – TLS, IPv6, IPv4 with IPsec
Audit Logging	Minimum data elements: date, time, patient ID, user ID
Data Integrity	SHA-1 or higher hashing algorithm FIPS PUB Secure Hash Standard (FIPS PUB 180-3)
Cross Enterprise Authentication	IHE Cross Enterprise User Assertion (XUA) with SAML
Record Treatment, Payment, and Health care operations disclosures	Minimum data elements: date, time, patient ID, user ID, and a description of the disclosure

2.   Data Architecture Overview

The following diagram shows a high-level system architecture and its four core component architecture including 1) business and application architecture, 2) data architecture, 3) technical architecture: Inter-HIE and Intra-HIE and 4) Privacy and Security Architecture. These four core component architectures are loosely coupled and interact with each other to realize a healthcare ecosystem. Desired system features (such as interoperability, scalability, efficiency and cost effectiveness, and quality of service) can be realized with coordination of four architecture components.
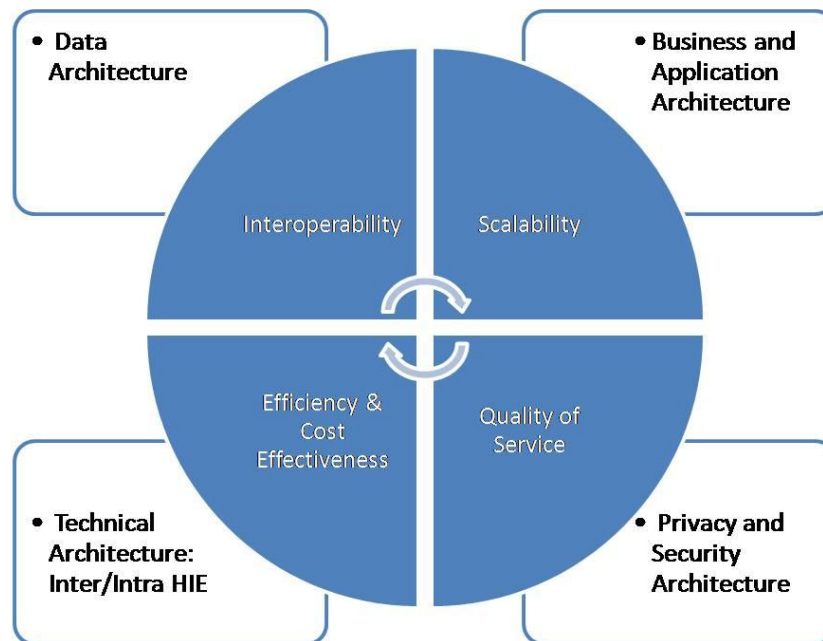
Figure 1 High-Level Architecture for Healthcare Ecosystem

Business and Application Architecture

Business and Application Architecture should include a Core Service stack comprising core components and subsystems supporting three core functionalities for health information exchange: 1) Privacy and Security, 2) Patient Discovery, and 3) Administrative/Clinical Data Exchange. This core service stack should be integrated with various health information systems via standardized APIs and adapters. On top of the Core Service stack, services implementing business workflows (Use cases) and applications are deployed via adapters. Each service on this stack supports a specific business workflow with trading partners such as providers, HIEs, Federal/State agencies, payors, and research communities.

Data Architecture

Data Architecture should address syntactic and semantic interoperability (Content Exchange and Vocabulary standards) for health information exchange by including but not limited to 1) vocabulary mapping engine, 2) data conversion/transformation, data consolidation, and 3) support of both structure and unstructured data

- Structured Data: Data which is structured with an abstract data model (e.g., HL7 CDA)
- Unstructured Data: Usually computerized information without a data model (or with a data model that is not easily usable by a computer program)

Technical Architecture

Technical Architecture provides core functionalities supporting business use cases/workflows, and services. It includes components for establishing a common, predictable, secure communication between health information systems. It should supports 1) Inter-HIE and 2) Intra-HIE.

Privacy and Security Architecture

Privacy and Security Architecture needs to include components for 1) Authentication, 2) Authorization, 3) Access Control and 4) Auditing

2.1.   Technical Considerations

The table below shows a list of criteria to be considered when designing a HIE Architecture. This list comes from combination of general practice for system architecture design and the result of the MHT's Environment Scan conducted in April.

Criteria	Description
Flexibility	The architecture and system components should be easy to modify for integration with other applications, software components, and environments. For flexibility, followings should be taken into consideration when design the HIE architecture - Flexible Programming: Language Independent + Platform Independent - Architectural Styles: Support various architectural design: for example, peer-to-peer, distributed and centralized - Reusable components with minimum modification
Interoperability & Interoperable Standards	The architecture and system components should be designed to assure syntactic and semantic interoperability for exchange of health information. The proposed HIE architecture should be designed by

	- Adopting existing and evolving standards addressing interoperability for health information exchange - Adopting HIT and standards adopted and/or recommended by HHS/ONC/FHA - Vocabulary Standards - Content Exchange Standards - Transport Standards - Privacy and Security Standards
Scalability	The architecture should be designed to scale up (rescaling in size and volume) as HIE grows with more stakeholders, additional connectivity, rapidly growing transaction/data volumes, newly added services supporting business use cases and workflows
Privacy and Security	The architecture should ensure protection of patients' privacy and the security of the information exchanged between stakeholders. This requires followings - Coordination with HIPAA - Coordination with HITECH Act - Coordination with DURSA (HHS/ONC/NHIN)
Liability	The architecture should ensure the local ownership of medical data and information
Cost Effective	The architecture must be designed for HIE sustainability
Other Quality of Service (QoS) Metrics	The architecture should also be designed considering other QoS elements including but not limited to - Performance - Availability - Ease of Use: The architecture must be designed in way that is easy to use, seamless, and have the same functionality and appearance to stakeholders
Business Use Case and Workflows	The architecture should ensure offerings of business use cases, workflows along with services for the stakeholders including but not limited to - HIE to HIE including state's report to Federal Public Health - Provider to Patient - Provider to Provider - Provider to Laboratory

| | ▪ Provider to Pharmacy |
| | ▪ Provider to Federal/State Public Health |

2.2.   Architectural Choices Overview

There are generally three architectures that are supported for Health Information Exchange, or HIE, including Federated, Centralized, and Hybrid Architectures. No matter which architecture is selected, the State of North Dakota should ensure that any and all vendor systems adhere to national standards (FHA, ONC, NHIN, HHS, etc) and utilize open standards, to ensure interoperability and support from the community (IHE, Integrating the Healthcare Enterprise standards have been established and embraced by many vendors in the HIE space).

Federated Architecture:
A Federated Architecture is a distributed architecture for HIE where the patient data remains at the provider level, and this patient data is not duplicated in a HIE central repository or database. In a Federated HIE model, there is no centralized database or centralized repository, thus allowing the Federated model to have a high security model (i.e., all patient data remains at each individual provider location, typically behind the provider's firewall and protected by existing provider security and systems, etc.). Patient data is queried and retrieved from each source system in a Federated Model for HIE, and the returned information is assembled and presented to the person or system querying for information.

Centralized Architecture:
A Centralized Architecture for HIE is one that has a centralized database, allowing all HIE members to access and utilize core services and data, including patient data. In a Centralized Model, the HIE is the data center and patient repository, and all patient data is synchronized from provider systems to the centralized database and 'router'. In this model, the HIE is fully responsible for privacy and security, as well as access controls to the patient data in the HIE, which can present some operational, legal and security hurdles that must be overcome.

Hybrid Architecture:
A Hybrid Architecture for HIE is one that utilizes the best of both the Federated and Centralized Architecture. The HIE, in a Hybrid Architecture model, acts as a clinical information coordinator, and responsibility for patient information and security is shared amongst the HIE participating members. It is important to note that patient data in a Hybrid Architecture stays on the source, or provider, systems and is staged on dedicated databases within the HIE. The State of North Dakota has stated a preference for a hybrid model.

2.3.   Nationwide Health Information Network Overview

An important aspect of HIE interoperability and meaningful use is the ability to connect with the Nationwide Health Information Network (NHIN) and be in full compliance with current and developing standards from Health and Human Services, the Office of the National Coordinator

(ONC) and the Federal Health Architecture (FHA). Installation and utilization of a certified and compliant NHIN Gateway, as well as standards-compliant systems and solutions, will ensure that the North Dakota State HIE can link with other NHIN HIEs, states, and Federal Agencies. Interoperability with other State and Federal networks, as well as other HIEs, will support the North Dakota State HIE in meeting the criteria for Meaningful Use.

2.3.1   Nationwide Health Information Network (NHIN)

The Nationwide Health Information Network (NHIN) comprises standards, services, and a trust fabric that enables the secure exchange of health information over the Internet. This critical part of the national health IT agenda will enable health information to follow the consumer, be available for clinical decision making, and support appropriate use of healthcare information beyond direct patient care, so as to improve population health.

To support providers wishing to achieve meaningful use of electronic health records (EHRs) and qualify for incentives under the Health Information for Clinical and Economic Health (HITECH) Act, technical and policy activities over the course of 2010 will expand the value of NHIN standards, services and trust fabric and extend the ability to securely exchange health information to a larger audience.

One instance of the NHIN standards, services and trust fabric has been in pilot testing through the NHIN cooperative, and is now ready for a limited production pilot to a broader community. This instance of the NHIN includes the robust technology and trust fabric necessary to support health information exchange among large nationwide organizations and federal entities. Entities that wish to exchange information with these partners must:

1. Execute a comprehensive trust agreement that governs the roles and responsibilities of exchange at this level. This agreement is called the Data Use and Reciprocal Support Agreement (DURSA)

2. Demonstrate that they can support a multi-point information exchange, and

3. Complete a validation and on-boarding process.

The Office of the National Coordinator for Health IT (ONC) believes the secure exchange of health information using NHIN standards, services and policies, with broad implementation, will help improve the quality and efficiency of healthcare for all Americans.[2]

2.3.2   Integration with and Participation on the Nationwide Health Information Network:

As listed above, to participate in the Nationwide Health Information Network, the State of North Dakota HIE must execute the DURSA agreement, demonstrate a multi-point information exchange, and complete a validation and on-boarding process. It is also of note that the State of North Dakota HIE *might* require a Federal Agency sponsor to participate on the NHIN (note: rules and regulations on connectivity to NHIN, as well as

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[2] Overview of the Nationwide Health Information Network by The Office of The National Coordinator (ONC)

requirements such as having an executive sponsor or Federal Sponsoring Agency are fluid and changing, thus this requirement may need further modification), therefore, it is recommended that the State of North Dakota HIE implement a NHIN use case and connectivity model to a Federal Agency as part of the Phase I implementation of the North Dakota HIE. By utilizing a Federal Agency use-case and sponsor, the North Dakota HIE can insure participation and compliancy with the NHIN at a Federal level, and thus utilize NHIN to connect to local and other state HIE initiatives and departments.

It is recognized that states and initiatives surrounding the State of North Dakota have plans or are implementing NHIN connectivity for both intra and inter-state connectivity. It is therefore recommended that the State of North Dakota HIE implement an NHIN Gateway for standards based inter and intra state connectivity, with the first use case to a Federal Agency. Additional NHIN connectivity to other states and HIEs can be added in a phased approach, including connectivity to the State of North Dakota, connectivity to Nebraska and the NEHii HIE initiative, connectivity to the two recognized Minnesota HIEs (HIE-Bridge and MN-HIE), and connectivity to the State of Wyoming. Additional States and HIE initiatives can be added in additional phases, including the addition of more Federal Agencies and Federal use cases.

2.3.3   Open Source NHIN CONNECT Gateway

It is furthermore recommended that the State of North Dakota HIE implement a standard CONNECT NHIN Gateway, as offered by the CONNECT Team of the Office of the National Coordinator (connectopensource.org). As CONNECT is the fully NHIN tested and compliant offering from the ONC and United States Government, the State of North Dakota HIE can insure fully compliancy and interoperability with NHIN by utilizing a NHIN Gateway based upon CONNECT standards.

CONNECT is an open source software solution that supports health information exchange – both locally and at the national level. CONNECT uses Nationwide Health Information Network (NHIN) standards and governance to make sure that health information exchanges are compatible with other exchanges being set up throughout the country.

This software solution was initially developed by federal agencies to support their health-related missions, but it is now available to all organizations and can be used to help set up health information exchanges and share data using nationally-recognized interoperability standards.

CONNECT can be used to:

- Set up a health information exchange within an organization
- Tie a health information exchange into a regional network of health information exchanges
- Tie a health information exchange into the NHIN

By advancing the adoption of interoperable health IT systems and health information exchanges, the country will better be able to achieve the goal of making sure all citizens

have electronic health records by 2014. Health data will be able to follow a patient across the street or across the country.[3]

As the CONNECT NHIN software is updated quarterly by the ONC and CONNECT Team, it is further recommended that the State of North Dakota HIE implement an NHIN Gateway either:

1. As a managed service from a CONNECT certified vendor, with full quarterly upgrades and compliancy insured or

2. Budget and staff internally for the North Dakota HIE to insure the NHIN Gateway, based upon CONNECT standards, is upgraded, patched, and supported quarterly to insure full compliancy and interoperability with NHIN.

2.3.4 Aligned with NHIN Direct Efforts

NHIN Direct is another initiative lead by ONC addressing use cases such as on provider-to-provider, provider-to-pharmacy, and/or provider-to-laboratory. The HIE architecture for the State of North Dakota should consider future inclusion of the outcome of this efforts.

"NHIN Direct is the set of standards, policies and services that enable simple, secure transport of health information between authorized care providers. NHIN Direct enables standards-based health information exchange in support of core Stage 1 Meaningful Use measures, including communication of summary care records, referrals, discharge summaries and other clinical documents in support of continuity of care and medication reconciliation, and communication of laboratory results to providers".[4]

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[3] From http://www.connectopensource.org

[4] From http://www.nhindirect.org

3 Proposed Technologies for Health Information Exchange Architecture

The following technologies will serve as a foundation for building the North Dakota HIE.

- Service Oriented Architecture (SOA)

  SOA is desired as a foundation of the HIE architecture. One of important of aspect of SOA is the separation of the service from its implementation.

- Federated Identity Management along with Single Sign On and Role Based Access Control (RBAC)
- Cloud Computing technology along with Virtualization technology
  - Infrastructure as a Service (IaaS)
  - Platform as a Service (Paas)
  - Software as a Service (Saas)
- Hybrid HIE Architecture – Combination of centralized and federated architectures
- Adoption of Open Source solutions with on-going development and support
- Syntactic and Semantic Interoperability
- Adoption of Enterprise Service Bus pattern for integration of heterogeneous health information systems
- SaaS (Software as a Service) based service offerings

	Proposed Technology						
	SOA	Federated Identity Management	Cloud Computing/ Virtualization	Hybrid Architecture	Adoption of Open Source Solutions	Adoption of Standards	ESB
Flexibility	√		√	√	√	√	√
Scalability	√	√	√	√		√	√
Interoperability	√	√				√	√
Privacy & Security	√	√		√		√	
Liability				√			
Cost Saving			√		√		√
Performance			√				
Availability	√		√				
Ease of Use			√				

3.1 Core Functionality

Following table shows a description on core functionalities, business needs, challenges, and recommendations.

Core Functionality	Business Needs	Challenges	Recommendations

Privacy and Security	HIPAA compliant system to ensure security and protecting patient privacy	• Disparate governance rules and policies on security and privacy in different healthcare organizations
		
		• Different authentication mechanisms
		
		• Locality of identities ➔ Not globally sharable
			• Public Key Infrastructure (PKI) based strong Authentication, Authorization, Access Control, and Auditing (4A)
			
			• Federated Identity Management
			
			   o Simplified authorization/registration process to multiple services across healthcare organizations
			
			   o Single Sign On
			
			   o Integrated Patient Health Information Protection
			
			• Role Based Access Control (RBAC)
			
			• Patient Consent Management System

Patient Discovery	"*Identifying A Patient*": Locating a patient and establishing the identity of mutual patients in different	• A lack of National Patient ID • Inconsistent demographic attributes among healthcare providers (or HIEs) and their	• Within a HIE (Intra-HIE Clinical Information Exchange): Distributed/Federated Patient Lookup • Across HIEs (Inter-HIE Clinical Information Exchange): Adopting NHIN

	healthcare domains	data sources • Disparate and disconnected MPIs and independent matching algorithms • Consumer privacy restrictions	Service Interface "Patient Discovery"
Administrative/ Clinical Data Exchange	"*Exchanging Clinical Information Securely*": Exchanging clinical data between different healthcare stakeholders	• Establishing co-relation between patient IDs from different healthcare stakeholders ➔ *Addressed by Patient Discovery* • Disparate and disconnected EHR systems using different communication protocols and data formats	• Within a HIE (Intra-HIE Clinical Information Exchange): Enterprise Service Bus (ESB) strategy to support various communication protocols (transport protocols) and disparate data formats (data transformation/conversion) • Across HIEs (Inter-HIE Clinical Information Exchange): Adopting NHIN Service Interfaces "Query for Documents" & "Retrieve Documents"

3.2   Privacy and Security

The State of North Dakota HIE should ensure all systems and services are fully compliant with all HIPAA regulations, and utilize standards based security mechanisms, including standardized encryption technologies. Industry-proven technologies such as Federated Identity Management with Role Based Access Controls should be considered for adoption to ensure data security and integrity. A high level of encryption, including Public Key Infrastructure (PKI) should be considered as an encryption standard, as well as the process of encrypting each and every message, regardless of location of the system (including within the HIE system). The utilization of standards based encryption

technologies such as PKI will ensure authenticity and non-repudiation of data by digitally signing each and every message.

Utilization of a Federated Identity Management Service, along with Role-Based Access Control (RBAC) framework, information and data is available to be shared across wide area security domains. Additionally, any and all security processes and systems should comply with any and all local, state and Federal laws (for example, the State of Minnesota has a strict Record Locator Law, with Patient Consent Management and opt-in opt-out services).

Integration of HIE services with a Federated Identity Management System, with Public Key Infrastructure and Role-Based Access Control, allows for interoperable clinical data exchange globally, with management retained locally.

3.3   Patient Consent Management

It is critical for the State of North Dakota Statewide HIE to have a Patient Consent Management system integrated into the Statewide HIE infrastructure. The ability for a patient to electronically, or via paper, opt-out of the Statewide HIE is an extremely critical workflow that the State should consider for inclusion into the HIE infrastructure.

3.4   Enterprise/Master Patient Index

In order to support Inter-HIE patient discovery, the North Dakota Statewide HIE can implement an eMPI, or Enterprise Master Patient Index, as a part of the core offering of the Health Information Exchange. If implemented, the eMPI should be fully integrated with the HIE offerings and systems, to allow for HIE-wide patient matching. For example, the eMPI should fully interact with the Record Locator Service to establish the mutual identity between patients from the local HIE, as well as other HIEs. The risks of not implementing an eMPI include having multiple records and patient data for the same patient that are not matched and utilized / coordinated for care.

3.5   Clinical Data Exchange

The State of North Dakota HIE could provide HIPAA-compliant clinical data exchange in both standard data formats, including CCR (Continuity of Care Record) and CCD (Continuity of Care Document). CCD has been selected as the standard for the Federal Health Architecture and NHIN, thus it is highly recommended that the State of North Dakota implement the CCD standard for clinical data input and output and clinical data exchange. Providers who are incapable of exporting and importing CCD documents from their EMR systems will either need to upgrade their EMR systems to allow for full CCD interoperability, or implement a custom translator service/interface for CCD compliancy. The State of North Dakota HIE should be aware of CCD interoperability as a substantial risk, as many providers who have an EMR are not capable of CCD compliancy, and the costs can be somewhat prohibitive to implement full CCD compliancy, especially for smaller providers and healthcare entities.

3.6   Record Locator Service

Modern patient care techniques and services demand instant access to a patient's disparate healthcare information. Instant access is realized with a system that accurately identifies all related information for an individual automatically, without human intervention. In general, a "Record Locator Service", or RLS, can be defined as an electronic index of patient identifying information. This RLS information directs providers to the location of the patient health records (usually held by healthcare organizations). Typically, the two core capabilities of an RLS are:

1) Identifying a patient within a community (HIE or RHIO) and/or in a remote communities and

2) Identifying the location (communities and/or healthcare provider facilities) of a patient's clinical data.

Users search for a patient with full or partial demographic information including first name, last name, date of birth, gender and zip code, and other search criteria.

4.   Proposed Health Information Exchange Architecture

The proposed HIE Architecture for the State of North Dakota is a standard-based hybrid architecture with: 1) combination of centralized and distributed (federated) registries/ services/applications and 2) centralized and de-centralized data.
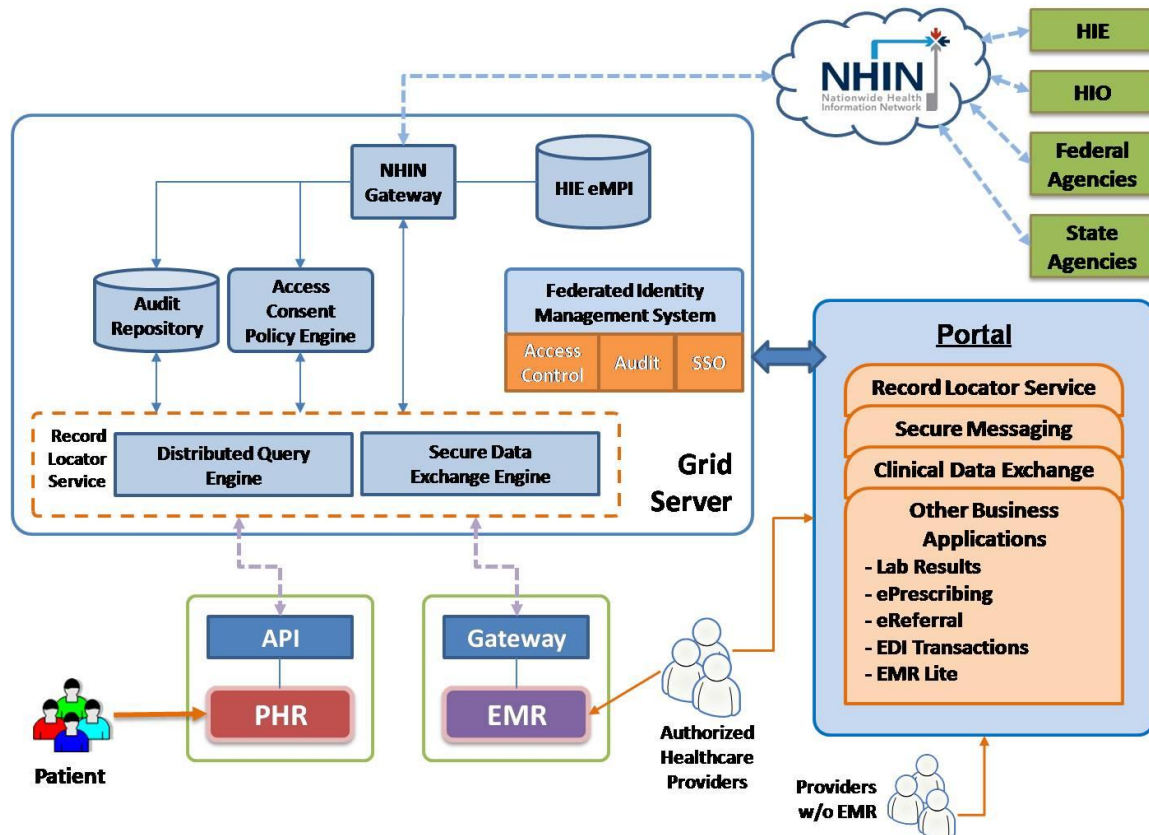
4.1   Registries, Engines and Subsystems for Hybrid HIE Architecture

The figure below shows a set of registries, engines, and subsystems to be included in a hybrid HIE architecture.
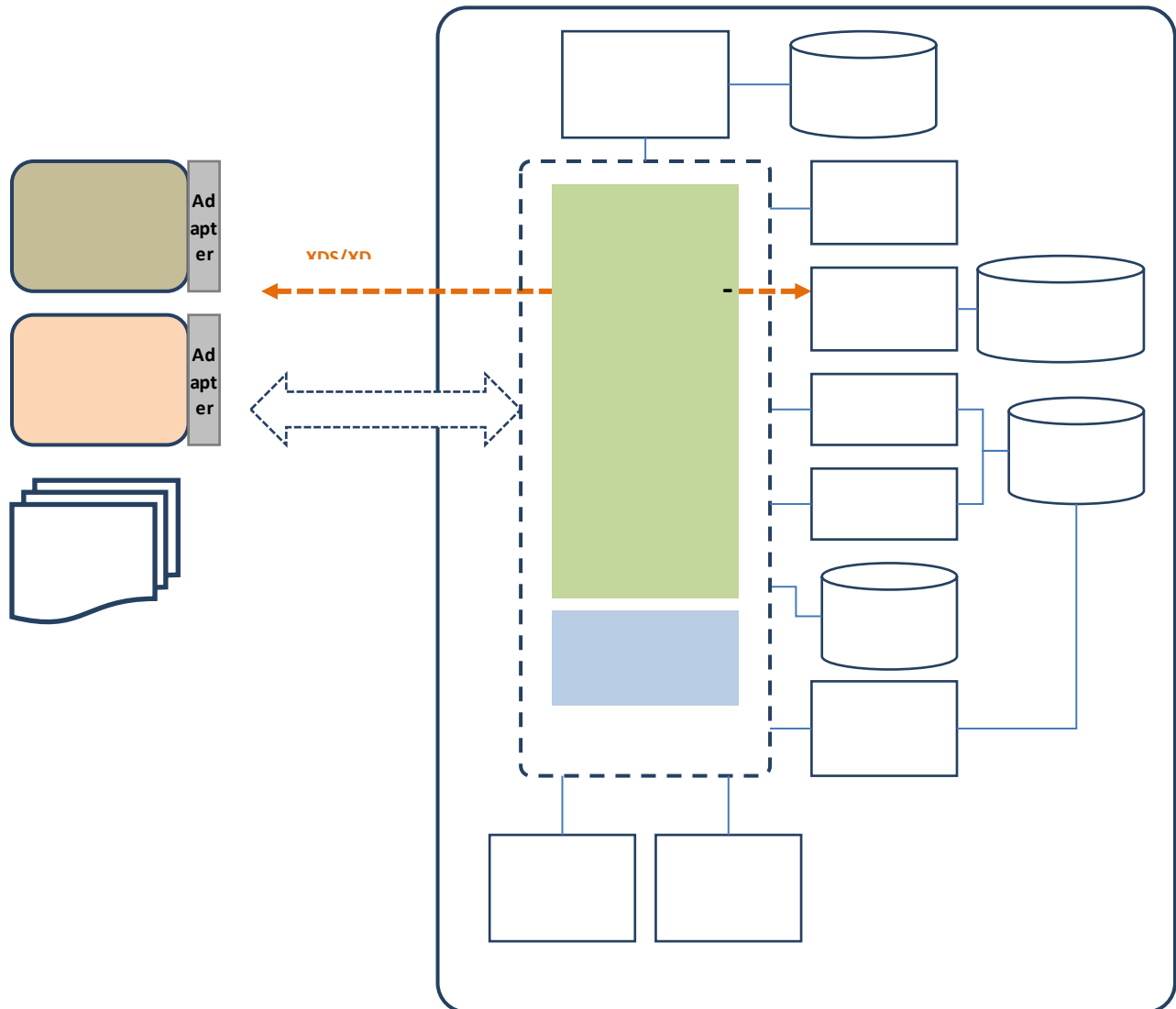
4.2   Provider Registry

A centralized provider registry supports 1) lookup, 2) create, 3) update of entries of healthcare providers (professionals and organizations). It should be integrated with National Provider Identifier (NPI) database. The provider Registry needs to be exposed through standard APIs such as SOAP and/or RESTful Web Services APIs. In the case that needs to deal with health information systems with proprietary APIs, an Enterprise Service Bus (ESB) engine needs be interfaced with the Provider Registry.

4.3   Consent Registry

The Consent Registry is a consistent source of a consumer's preferences, thereby enabling patient engagement and provider access to clinical information. The registry might need to be connected to any existing consent registries. It should comply with the NHIN exchange model - adoption of XACML for the format of Access Consent Policies (ACPs) and HITSP TP30 "HITSP Manage Consent Directives Transaction Package" which adopts IHE's Basic Patient Privacy Consents (BPPC) which is HL7 CDA based. For the exchange of Consent document, following IHE profiles should be adopted: IHE Cross-Enterprise Document Sharing (XDS) document sharing protocol and IHE Cross-Enterprise Document Reliable Interchange (XDR).

4.4   Web Services Registry (UDDI)

For both Inter-HIE and Intra-HIE transactions, a set of Web Services endpoints should be registered and available on a service registry (the Service Registry) for trading partners (state stakeholders, federal agencies, or HIEs) to locate and utilize the statewide Web Services. It should be an implementation of the OASIS's Universal Description, Discovery, and Integration (UDDI) registry specification.

4.5   Web Services Endpoints and Messaging

It should be designed based on the Service Oriented Architecture (SOA) and needs to adopt SOAP based implementation of the SOA. The rationale behind adopting Web Services technology is as follows. Web Services is a technology that has recently emerged as a standard communication platform to overcome the interoperability problems. One of the key features of the Web Services technology is an ability to wrap existing resources (such as electronic medical records, scanned images, lab results etc) and expose them as services, available to other trading partners. This feature enables a healthcare enterprise to address the interoperability problems of their legacy/proprietary healthcare information systems.

All business use cases and workflows should be developed as standard SOAP or REST-ful Web Services and should be exposed through the Service Registry. A GUI based management tool should be built on top of the Service Registry to support management of the Service Registry: 1) register, 2) modify, and 3) delete etc.

4.6   Integration and Message Transformation

HIE architecture should leverage Web Services standard technology (WSDL, SOAP, and UDDI) to realize SOA - defining, publishing, and using web services. It also should implement Web Services profiles (WS-I Basic Profiles and WS-I Security Profiles) as a standard messaging platform for the XML-based messaging exchange. It also should be able to address heterogeneity of the underlying database systems and health information systems (HIS)

5.   Value Proposition: Business Use Case and Service Offerings

The North Dakota Health Information Exchange has the opportunity to provide improved workflows, patient outcomes, improved care, and full meaningful use compliancy. A critical part of meaningful use is the ability to exchange clinical data between providers within the North Dakota Health Information Exchange as well as between North Dakota and surrounding states, surrounding HIEs, and Federal Agencies

5.1   Initial Data Elements for HIE exchange From the Environmental Scan

One of the questions posed to the Environmental Scan participants was "If this HIE work had to be done in stages, what are data elements you would desire in the first release?" The feedback was fairly consistent across the participants. Most indicated they wanted a fully function HIE from the beginning but understood that may not be financially possible. The data elements most often citied as most desirable in the first release include:

- Patient demographics
- Chief complaint
- Medications
- Allergies
- Latest labs and/or radiology results
- Immunizations

In later releases, participants would like to see the following data elements included:

- Quality indicators
- Medical history
- Disease management information
- Public health reporting
- Peer review
- Trending and benchmarking

5.2   User Stories

Actors	Use Stories
HIE to HIE	- Cross-State exchange of health information - HIE to Federal Agencies (CMS, SSA, DoD, VA, IHS etc) - Provider's Quality Measures Reporting to CMS over NHIN (PQRI) - Provider's Quality Measure Reporting to State over NHIN (PQRI) - State's public health data reporting to CDC (GIPSE) - Medicaid Connectivity to CMS

	▪ Medicare Connectivity to CMS
Provider to Patient	▪ Patient Health Record ▪ Patient Record Access Consent Management
Provider to Provider	▪ Electronic Referrals ▪ Electronic Disease reporting ▪ Clinical Messaging
Provider to Laboratory	▪ Electronic Lab Ordering ▪ Electronic Lab Results Reporting
Provider to Pharmacy	▪ Electronic Prescribing
Provider to Public Health	▪ Electronic immunization reporting ▪ Electronic Disease reporting
Provider to Payors	▪ Eligibility ▪ Claims ▪ Prior Authorization

5.3 Specific Use Cases for the State of North Dakota Statewide HIE

Of particular relevance are use cases. During the environmental scan a number of themes became abundantly clear. Satisfying the needs of these use cases will improve HIE adoption rates and drive toward sustainability.

5.4 Emergency use case

When a patient is admitted to an emergency room, immediate access to basics like immunization, current medications, recent lab histories and allergies can make a real difference in the quality of patient care as well as the efficiencies gained within the provider institution.

5.5 Continuity of Care

This is particularly true for patients sent for tertiary treatment or transferred to another type of care (long-term care, referral to the state hospital, etc.) Additionally, many of the participants along the Minnesota border expressed concerns related to patients that cross state borders seeking care. They were concerned that patient information could not be exchanged freely between states. Similar opportunities exist for patients along other North Dakota borders as well as transient citizens such as snow birds who travel to Florida or Arizona.

5.6   e-Prescribing

The ability for providers to have electronic prescribing, with medication history, could be a use case for strong consideration by the State of North Dakota and the North Dakota HIE. The migration of providers from a paper based or semi-electronic prescribing process to a fully integrated, electronic prescribing process (with medication history) could provide an immediate positive impact on the quality of care of patients in North Dakota.

5.7   EMR Light, or SaaS-based EMR

Providers in the State of North Dakota are working towards EMR compliancy, however, the State and Statewide HIE should consider a lightweight, Software As A Service (SaaS) based Electronic Medical Record for inclusion in the offering and use cases for the Statewide Health Information Exchange. Depending on the offering and associated funding models, a lightweight EMR offering could provide those providers who are reluctant, lack financial or human resources or are otherwise technology resistant, to participate in the HIE and collaborate.

6   Continuity of Care Document Provisions

The Continuity of Care Document contains 17 primary data fields. The North Dakota HIE plans to satisfy all Meaningful Use requirements by building the capacity to exchange all CCD data elements as defined for each stage of Meaningful Use.

1. **Header:** Defines the type of document being created, who the document is regarding (patient, physician, author) and how the document relates to other existing documents (if applicable).
2. **Purpose:** States the reason the document was generated, but only if a specific purpose is known (i.e., a referral, transfer, or by request of the patient).
3. **Problems:** Provides a list of relevant clinical problems, both current and historical, that are present for the patient at the time the document was created.
4. **Procedures:** Provides a list of all relevant and notable procedures or treatments, both current and historical, for the patient.
5. **Family History:** Gives relevant family health information that may have an impact on the patient's healthcare risk profile.
6. **Social History:** Describes the patient's lifestyle, occupation, and environmental health risks plus patient demographics such as marital status, ethnicity and religion.
7. **Payers:** Provides payment and insurance data pertinent to billing and collection, plus any authorization information that might be required.
8. **Advance directives:** Includes information about wills, healthcare proxies and resuscitation wishes, including both patient instructions and references to external documents.
9. **Alerts:** Provides a list of allergies and adverse reactions that are relevant for current medical treatment.
10. **Medications:** Provides a list of current medications and relevant historical medication usage.
11. **Immunizations:** Gives information the patient's current immunization status plus pertinent historical information about past immunizations.
12. **Medical Equipment:** Provides a list of medical equipment and any implanted or external devices relevant to patient treatment.
13. **Vital Signs:** Details information about vital signs for the time period including at a minimum the most recent vital signs, trends over time, and a baseline.
14. **Functional Stats:** Detailed information about what is normal for the patient, deviations from the norm (both positive and negative) and extensive examples.
15. **Results:** Lists lab and procedure results, and at a minimum, lists abnormal results or trends for the time period.
16. **Encounters:** Details relevant past healthcare encounters including the activity and location.
17. **Plan of Care:** Lists active, incomplete or pending activities for the patient that are relevant for ongoing care - including orders, appointments, procedures, referrals and services.

7 Health Information Exchange Strategies

The North Dakota Technical Infrastructure Domain Team is recommending the following strategies be included in the North Dakota Health Information Exchange Strategic and Operational Plan.

7.1 Stage 1 Services

The following services will be in stage 1 of the HIE:

- e-Prescribing
- Clinical lab results electronically
- Health department immunizations, syndromic surveillance, and notifiable lab results
- CCD requirements for stage 1 Meaningful Use

7.2 Determine the HIE Architecture

The following strategies for determining the HIE architecture will be employed:

7.2.1 The HIE needs to be architected and constructed with all required Meaningful Use data elements for each stage

7.2.2 The HIE should be designed as a hybrid model with the following data elements stored centrally
- Patient demographics
- Problem list
- Allergies
- Current medications

7.2.3 The remaining data elements of the Meaningful Use requirements will be stored at the provider level and the state owned *Initiate* master patient index will be used to locate specific patient information upon authorized request

7.2.4 The HIE will allow for the bi-directional exchange of healthcare information as required by Meaningful Use

7.2.5 The HIE will provide a single standard method of access to connect to interoperable and certified EHRs. It will be the responsibility of each provider to connect their EHR technology to connect to the HIE

7.2.6 The HIE needs to have a robust and easy to use patient portal where patients can access their medical information when and from where they determine

7.2.7 The HIE needs to be constructed so that stakeholders can choose from a list of services when connecting to the HIE. These services may include:
- Patient Portal
- Orders
- Quality Reporting
- E-Prescribing Function
- Provider Registry

7.3   Nationwide Health Information Network (NHIN)

The following strategies for connecting to NHIN will be employed:

- HITAC will execute the Data Use and Reciprocal Support Agreement (DURSA) with DHHS on behalf of all North Dakota providers
- The North Dakota Health Information Exchange will provide the primary connection to the NHIN for all providers in North Dakota
- Patients from other states or North Dakota patients seeking treatment outside of North Dakota will be connected to the North Dakota Health Information Exchange through the NHIN

7.4   Proposed Technologies

The following strategies for determining the technologies supporting the HIE are:

- e-Prescribing
- Reporting of structured lab results
- Patient care summaries
- Stage 1 requirements for supporting the Continuity of Care Document (CDD)
- 2011 Meaningful Use quality reporting requirements
- Provide web portal (ASP model) by which providers can share health information (such as medication history) and by which patients can view their records
- Provide ASP EMR (such as "EMR lite") that could be used by providers with or without their own EMR system—would need to be interoperable
- Connect to and integrate with other systems such as EMR and PHR

Appendix A.   Summary of Meaningful Use Certification Criteria for HIE

CMS and ONC Final Rule Compliant

	Category	Certification Criteria	Description	Standards	HIE Stage 1
1	General	Drug-drug, drug-allergy interaction checks - Notifications	Automatically and electronically generate and indicate in real-time, notifications at the point of care for drug-drug and drug-allergy contraindications based on medication list, medication allergy list, and computerized provider order entry (CPOE)	N/A	√
2	General	Drug-drug, drug-allergy interaction checks - Adjustments	Provide certain users with the ability to adjust notifications provided for drug-drug and drug-allergy interaction checks.	N/A	√
3	General	Drug-formulary checks	Enable a user to electronically check if drugs are in a formulary or preferred drug list		√
4	General	Maintain up-to-date problem list	Enable a user to electronically record, modify, and retrieve a patient's problem list for longitudinal care	45 CFR 162.1002(a)(1) & SNOMED CT	√
5	General	Maintain active medication list.	Enable a user to electronically record, modify, and retrieve a patient's active medication list as well as	N/A	√

#					
			medication history for longitudinal care		
6	General	Maintain active medication allergy list	Enable a user to electronically record, modify, and retrieve a patient's active medication allergy list as well as medication allergy history for longitudinal care.		√
7	General	Record and chart vital signs - Vital Signs	Enable a user to electronically record, modify, and retrieve a patient's vital signs including, at a minimum, height, weight, and blood pressure		
8	General	Record and chart vital signs - Calculate body mass index	Automatically calculate and display body mass index (BMI) based on a patient's height and weight		
9	General	Record and chart vital signs - Plot and display growth charts	Plot and electronically display, upon request, growth charts for patients 2-20 years old.		
10	General	Incorporate laboratory test results--(1) Receive results	Electronically receive clinical laboratory test results in a structured format and display such results in human readable format		√
11	General	Incorporate laboratory test results– (2) Display test report	Electronically display all the information for a test report	42 CFR 493.1291(c)(1) through (7)	√

		information			
1 2	General	Incorporate laboratory test results--(3) Incorporate results	Electronically attribute, associate, or link a laboratory test result to a laboratory order or patient record		√
1 3	General	General Patient Lists	Enable a user to electronically select, sort, retrieve, and generate lists of patients according to, at a minimum, the data elements included in: (1) Problem list; (2) Medication list; (3) Demographics; and (4) Laboratory test results.		√
1 4	General	Medication reconciliation.	Enable a user to electronically compare two or more medication lists		√
1 5	General	Submission to immunization registries	Electronically record, modify, retrieve, and submit immunization information in accordance with: (1) The standard (and applicable implementation specifications) specified in §170.205(e)(1) or §170.205(e)(2); and (2) At a minimum, the version of the standard specified in §170.207(e).	[Content] HL7 2.3.1 or HL7 2.5.1 and [Vocabulary] HL7 Standard Code Set CVX	
1	General	Public health	Electronically record, modify,	[Content] HL7 2.3.1 or	

6		surveillance	retrieve, and submit syndrome-based public health surveillance information in accordance with the standard (and applicable implementation specifications)	HL7 2.5.1	
1 7	General	Patient-specific education resources	Enable a user to electronically identify and provide patient-specific education resources according to, at a minimum, the data elements included in the patient's: problem list; medication list; and laboratory test results; as well as provide such resources to the patient		
1 8	General	Automated measure calculation	For each meaningful use objective with a percentage-based measure, electronically record the numerator and denominator and generate a report including the numerator, denominator, and resulting percentage associated with each applicable meaningful use measure		
1 9	General - Security and Privacy	Access control	Assign a unique name and/or number for identifying and tracking user identity and establish controls that permit only authorized users to access electronic health information		√

2 0	General – Security and Privacy	Emergency access	Permit authorized users (who are authorized for emergency situations) to access electronic health information during an emergency		√
2 1	General – Security and Privacy	Automatic log-off	Terminate an electronic session after a predetermined time of Inactivity		√
2 2	General – Security and Privacy	Audit log (1)— Record actions	Record actions related to electronic health information√		
2 3	General – Security and Privacy	Audit log (2)— Generate Audit Log	Enable a user to generate an audit log for a specific time period and to sort entries in the audit log according to any of the elements specified in the standard at §170.210(b).		√
2 4	General – Security and Privacy	Integrity.	(1) Create a message (2) Verify upon receipt of electronically exchanged health information that such information has not been altered (3) Detection. Detect the alteration of audit logs	A hashing algorithm with a security strength equal to or greater than SHA-1	√
2 5	General – Security and Privacy	Authentication.	Verify that a person or entity seeking access to electronic health information is the one claimed and is authorized to access such information		√

26	General - Security and Privacy	General encryption	Encrypt and decrypt electronic health unless the Secretary determines that the use of such algorithm would pose a significant security risk for Certified EHR Technology	Any algorithm identified NIST (FIPS 140-2)	√
27	General - Security and Privacy	Encryption when exchanging electronic health information	Encrypt and decrypt electronic health information when exchanged	Any	√
28	General - Security and Privacy	Optional Accounting of disclosures	Record disclosures made for treatment, payment, and health care operations	45 CRF 164.501	
29	Ambulatory /Inpatient	Computerized provider order entry	Enable a user to electronically record, store, retrieve, and modify, at a minimum, the following order types: (1) Medications; (2) Laboratory; and (3) Radiology/imaging.		
30	Ambulatory	Electronic prescribing	Enable a user to electronically generate and transmit prescriptions and prescription-related information	[Content] NCPDP v8.1 or NCPDP v10.6 [Vocabulary] RxNorm	√
31	Ambulatory /Inpatient	Record demographics	Enable a user to electronically record, modify, and retrieve patient demographic data		√

			including preferred language, gender, race, ethnicity, and date of birth. Enable race and ethnicity to be recorded		
3 2	Ambulatory	Patient reminders	Enable a user to electronically generate a patient reminder list for preventive or follow-up care according to patient preferences based on, at a minimum, the data elements included in: (1) Problem list; (2) Medication list; (3) Medication allergy list; (4) Demographics; and (5) Laboratory test results.		
3 3	Ambulatory /Inpatient	Clinical decision support - (1) Implement rules	Implement automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) based on the data elements included in: problem list; medication list; demographics; and laboratory test results.		
3 4		Clinical decision support - (2) Notifications	Automatically and electronically generate and indicate in real-time, notifications and care suggestions based upon clinical decision support rules		

35	Ambulatory /Inpatient	Electronic copy of health information	Enable a user to create an electronic copy of a patient's clinical information, including, at a minimum, diagnostic test results, problem list, medication list, and medication allergy list in: (1) Human readable format; and (2) On electronic media or through some other electronic means	[Content] HL7 CDA Release 2, CCD or ASTM CCR	√
36	Inpatient	Electronic copy of discharge instructions	Enable a user to create an electronic copy of the discharge instructions for a patient, in human readable format, at the time of discharge on electronic media or through some other electronic means		
37	Ambulatory	Timely access	Enable a user to provide patients with online access to their clinical information, including, at a minimum, lab test results, problem list, medication list, and medication allergy list.		√
38	Ambulatory	Clinical summaries	Enable a user to provide clinical summaries to patients for each office visit that include, at a minimum, diagnostic test results, problem list, medication list, and medication allergy list. If the clinical summary is provided		√

			electronically it must be: (1) Provided in human readable format; and (2) Provided on electronic media or through some other electronic means		
3 9	Ambulatory /Inpatient	Exchange clinical information and patient summary record– (1) Electronically receive and display	Electronically receive and display a patient's summary record, from other providers and organizations including, at a minimum, diagnostic tests results, problem list, medication list, and medication allergy list. Upon receipt of a patient summary record formatted according to the alternative standard, display it in human readable format.	[Content] HL7 CDA Release 2, CCD or ASTM CCR	√
4 0	Ambulatory /Inpatient	Exchange clinical information and patient summary record– (1) Electronically transmit	Enable a user to electronically transmit a patient summary record to other providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, and medication allergy list	[Content] HL7 CDA Release 2, CCD or ASTM CCR	√
4 1	Ambulatory /Inpatient	Calculate and submit clinical quality measures– (1) Calculate	(i)Electronically calculate all of the core clinical measures specified by CMS for eligible professionals. (ii) Electronically calculate, at a minimum, three clinical quality measures specified		

			by CMS for eligible professionals, in addition to those clinical quality measures		
4 2	Ambulator y /Inpatient	Calculate and submit clinical quality measures	Enable a user to electronically submit calculated clinical quality measures	CMS PQRI	
4 3	Inpatient	Reportable lab results	Electronically record, modify, retrieve, and submit reportable clinical lab results	[Content] HL7 2.5.1 [Vocabulary] LOINC v2.27	
4 4	Inpatient	Advance directives	Enable a user to electronically record whether a patient has an advance directive		

Appendix B.   Related Acronyms

ANSI	American National Standards Institute
CCD	Continuity of Care Document
CCHIT	Certification Commission for Health Information Technology
CCR	Continuity of Care Record
CDA	Clinical Document Architecture
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CMS	Centers for Medicare & Medicaid Services
CPOE	Computerized Provider Order Entry
EHR	Electronic Health Record
FIPS	Federal Information Processing Standards
GIPSE	Geocoded Interoperable Population Summary Exchange
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996
HIT	Health Information Technology
HITECH	Health Information Technology for Economic and Clinical Health
HITSP	Healthcare Information Technology Standards Panel
HL7	Health Level Seven
ICD	International Classification of Diseases
ICD-9-CM	International Classification of Diseases, 9th Revision, Clinical Modification
ICD-10-PCS	International Classification of Diseases, 10th Revision, Procedure Coding System
ICD-10-CM	International Classification of Diseases, 10th Revision, Clinical Modification
IHS	Indian Health Service
LOINC	Logical Observation Identifiers Names and Codes
NCPDP	National Council for Prescription Drug Programs
NLM	National Library of Medicine
NIST	National Institute of Standards and Technology
ONC	Office of the National Coordinator for Health Information Technology
PQRI	Physician Quality Reporting Initiative
REST	Representational state transfer
SNOMED-CT	Systematized Nomenclature of Medicine Clinical Terms
SOAP	Simple Object Access Protocol
UCUM	Unified Code for Units of Measure
UMLS	Unified Medical Language System
XML	eXtensible Markup Language